

REMARKS

In an interview with the Examiner on February 7, 2008 the Examiner suggested amendments to the claims to overcome the rejections based on Aubaniac and Merchant. Additionally, after subsequent investigation, the Examiner informed Applicant's undersigned attorney that the 102(e) rejection based on Aram was being removed. Accordingly, on March 17, 2008, Applicant electronically filed a response with the amendments suggested by the Examiner to overcome the Aubaniac and Merchant rejections, and presumably place the application in form for allowance. However, on March 18, 2008 an office action issued that did not consider the amendments submitted March 17, 2008. Additionally, the new office action included a new rejection based on newly cited art.

Since the March 18th office action did not consider Applicant's March 17th amendment, it does not appear that the amendment has been entered. Accordingly, Applicant's undersigned attorney is unclear as to the status of the claims. Therefore, the amendments set forth above are claim amendments with respect to the claims that were made with the Response filed July 17, 2007, which were the claims that the Examiner considered in the March 18th Office Action.

Merchant 6,616,696

With regard to Merchant, the only independent claim under rejection was claim 78. As discussed during the interview, the amendments as set forth above clearly distinguish Applicant's device from the prosthesis illustrated in Fig. 4 of Merchant. Specifically, claim 78 recites that the second portion has a width at an intersection with the first portion and a length, wherein the length is greater than the width. As recognized by the Examiner, Merchant clearly does not teach or suggest a prosthesis having such a configuration.

Aubaniac WO 87/02882

With regard to Aubaniac, the independent claims under rejection were claims 14, 50, 78 and 84. As discussed during the interview, the amendments to claims 14, 50 and 78, as set forth above, clearly distinguish Applicant's device from the prosthesis illustrated in Figs 21-24 of Aubaniac. Additionally, as discussed during the interview, claim 84 was previously amended to incorporate the features of claim 99, and the Examiner had previously indicated that the features of claim 99 were patentable over Aubaniac. See Official Action dated May 21, 2007 and Response dated July 17, 2007.

German Pat. DE2901009

The only remaining rejection is based on the newly cited German reference DE2901009. The German reference was published in German, and Applicant was unable to identify a corresponding English equivalent application. Accordingly, Applicant had the German reference translated into English. A copy of the English translation is attached as Attachment A for the Examiner's reference.

The German reference is directed to a total knee replacement prosthetic. The object of the German device is to provide a total knee replacement prosthetic that can be adjusted to a variety of sizes, so that the same prosthesis can be used for patients of differing sizes. See pg. 4, ¶¶ 3-4.

To accomplish this objective, the device in DE2901009 provides a total knee replacement prosthesis in which the femoral component is split into two parts.

	Element name in description	Function
1 st part	shaft 8	rod to be inserted into femur to attach prosthetic to patient
	middle part 13	mounting block for connecting two parts of the femoral prosthetic
	shells 12	replacement surface for condyles (i.e. femoral element for femoral-tibial joint)
2 nd part	insert 17	femoral element for patello-femoral joint)

The shaft 8, mounting block 13 and replacement condylar surface 12 are formed as a single piece. See last sentence of 3rd full ¶ on page 6.

Figures 3-4 show that the insert 17 slides into the gap between the condylar portions 12. By allowing the insert to slide inwardly or outwardly, the prosthetic can be enlarged or contracted to accommodate differences in patient size.

The insert 17 slides inwardly or outwardly in grooves 16. Specifically, the insert 17 has a pair of legs 21 that are parallel to one another. The parallel legs 21 ride in a pair of parallel grooves 16 formed in the mounting block 13. See 5th full ¶ on pg 6.

More specifically, the insert has a pair of legs that are "limited on the outside by parallel lateral surfaces 22 each, which carry a rib 23 along the rear edge." The ribs 23 are shaped to correspond to the grooves 16 so that the legs can slide in the grooves. Figures 3-7 show the parallel legs 21 progressively sliding into the grooves 16 of the mounting block.

As can be seen from the foregoing, the insert 17 in DE 2901009 is simply a sliding element of an adjustable total knee replacement system. The insert is not intended to be used as a prosthetic by itself, and has no independent function outside the intended system. Insert 17 is specifically designed and configured to attach with the mounting block 13 of the system.

The insert is not intended to be mounted directly onto the bone of a patient. In fact, since the legs 21 of insert 17 are parallel legs, the legs do not follow the anatomy of the knee. Therefore, it would not be possible to use the insert 17 separate from the system in DE2901009.

Additionally, DE2901009 does not teach or suggest the idea of modifying a patella-femoral prosthetic to incorporate an intercondylar notch element as taught by Applicant. Although the insert 17 in DE2901009 includes extension legs 21, these have nothing to do with the idea of incorporating an intercondylar notch element.

The system in DE2901009 is directed to a total knee replacement. Therefore, every articular surface is necessarily replaced. As a result, there is no thought or concern about the intercondylar notch.

In contrast, Applicant's system is directed to a partial knee replacement. Historically, during patella-femoral arthroplasty, a prosthetic was inserted to replace the trochlear groove portion of the femur. Such a procedure is a common procedure performed countless times over the past decades. However, Applicant recognized that one of the problems associated with this common procedure relates to deep knee flexion. Accordingly, Applicant designed a modification of the known patella-femoral prosthetics to incorporate one or more extensions that extend along the intercondylar notch. This improvement has resulted in a patella-femoral prosthetic that provides improved motion when the patient bends his or her knee in deep flexion.

To date, none of the numerous references cited during prosecution have any teaching or suggestion of a trochlear groove element designed to improve deep knee flexion after a patella-femoral arthroplasty. And as discussed above, DE2901009 is directed to a total knee replacement in which all of the articular surfaces are replaced, so there would be none of the issues related to a partial knee replacement.

As discussed above, the structure and function of Applicant's device is significantly different from the devices. The differences are reflected in the claims.

Referring to the claims, claim 1 recites a femoral prosthetic having a trochlear groove portion and an intercondylar notch portion. Claim 1 specifically states that it has a posterior surface configured to engage the femur. Since the insert 17 in DE2901009 is specifically adapted to cooperate with the total knee replacement system, the posterior side of insert 17 has a pair of guides that cooperate with the mounting block 13 of the system. In other words, the insert does not have a posterior side configured to engage the femur. Further still, as discussed above, there would be no motivation to modify insert 17 to have a posterior side for engaging the femur because the insert 17 does not follow the anatomy of the femur—which makes sense, because it is designed to cooperate with other parts of the total knee replacement system. Since DE2901009 does not teach or suggest the features of claim 1, Applicant requests that the Examiner reconsider the rejection of claim 1 and dependent claims 2-3 and 5.

Similarly, claim 14 recites a femoral prosthesis having a medial or lateral extension configured to extend along the intercondylar notch and engage a substantial portion of the medial or lateral portion of the intercondylar notch. Since DE2901009 does not teach or suggest such features, Applicant requests that the Examiner reconsider the rejection of claim 14 and dependent claims 15-24.

Claim 50 recites a femoral prosthesis having a body portion configured to

overlie a portion of the trochlear groove and an intercondylar notch portion having a pair of divergent legs. In contrast, the device in DE2901009 has an insert 17 with a pair of parallel legs 21. As discussed in the patent, the parallel legs 21 allow the total knee system to adjust by sliding the insert into the mounting block 13. In fact, if the legs 21 were divergent, the insert 17 would not be able to slide in and out of the block 13, which is the whole point of the invention in DE2901009. Accordingly, Applicants request that the Examiner reconsider the rejection of claim 50 and dependent claims 51-58.

Claim 59 recites a prosthesis having a portion configured to engage a portion of the intercondylar notch. As discussed above in connection with claims 1 and 14, DE2901009 does not teach or suggest such a feature. Additionally, claim 59 recites that the prosthesis includes first and second extensions that flare outwardly medially or laterally and posteriorly. Claim 51 further recites that the extensions diverge to overlie a substantial portion of the intercondylar notch. As discussed above in connection with claim 50, DE2901009 does not teach or suggest a prosthesis having diverging extensions overlying the intercondylar notch. In light of the foregoing, Applicant requests that the Examiner reconsider the rejection of claim 59 and dependent claims 60-64 and 65-68.

Claim 69 recites a femoral prosthesis having an intercondylar notch portion comprising a medial or lateral extension that curves along substantially its entire length. As discussed above in connection with claim 50, the insert 17 has legs 21 that are straight and parallel. In contrast, claim 69 recites that the intercondylar notch portion curves along substantially its entire length. Accordingly, Applicant requests that the Examiner reconsider the rejection of claim 69 and dependent claims 70-76.

Claim 78 recites that the prosthesis has a portion configured to overlie a portion that flares either medially or laterally to overlie the medial or lateral portion of the intercondylar notch. As discussed above, the insert 17 has legs 21 that are parallel and

therefore are not configured to overlie the intercondylar notch. The insert may have legs that project outwardly, but the insert does not have a portion that flares medially or laterally to overlie the medial or lateral portion of the intercondylar notch. Accordingly, Applicant requests that the Examiner reconsider the rejection of claim 78 and dependent claims 79-83.

With respect to claim 84, the claim recites a prosthesis having medial and lateral extensions extending along the intercondylar notch. Claim 84 specifies that the medial extension is transverse the lateral extension. As discussed above, in DE2001009 the legs 21 of insert 17 are parallel to operate as a guide for the system so that the system can be expanded and contracted. Accordingly, DE2901009 does not teach or suggest a medial extension that is transverse a lateral extension. Therefore, Applicant requests that the Examiner reconsider the rejection of claim 84 and dependent claims 85-98.

In light of the foregoing, Applicant believes that this application is in form for allowance. The Examiner is encouraged to contact Applicant's undersigned attorney if the Examiner believes that issues remain that would prevent the Examiner from examining the claims.

Patent Application No. 10/773,684

Respectfully submitted,

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ATTACHMENT A

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(54) Title: **Knee Joint Prosthesis**

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ORIGINAL INSPECTED

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Knee Joint Prosthesis

HAMBURG, January 09, 1979
D/mi

p 9053/78

Patent Claims

1. Knee joint prosthesis with at least one femoral condyle-side joint shell participating in the formation of the patellar sliding surface and with an insert extending the patellar sliding surface in the upward direction, characterized in that the said insert (2, 17) is connected to the joint shell (1, 12) by a said guide means (3, 4, 16, 23) guaranteeing a continuous sliding transition.
2. Prosthesis in accordance with claim 1, characterized in that the said guide means (3, 4) are formed by a joint, which is movable about a parallel axis that is essentially parallel to the axis of the knee joint.
3. Prosthesis in accordance with claim 2, characterized in that the joint is also set up for a motion about an axis extending essentially at right angles to the patellar sliding surface (Figure 2).
4. Prosthesis in accordance with claim 1, characterized in that in case of a design as a total prosthesis with a said upper intracondylar prosthesis part (6), which is bifurcated for receiving a joint neck (26) of the said lower prosthesis part (5) and has said joint shells 12 formed on both sides of the intermediate space formed by the said bifurcation and forms a said patellar sliding surface on these [joint shells], which said patellar sliding surface is extended above the said intermediate space by a said insert (17), the said insert (17) has a said extension (2), which leads to between the said joint shells (12) and carries the said guide means (23).
5. Prosthesis in accordance with claim 4, characterized in that the said extension (20) is bifurcated and participates in the formation of the said patellar sliding surface on both sides of the said intermediate space.
6. Prosthesis in accordance with claim 4 or 5, characterized in that the said guide means are formed by a said groove (16) and said tongue (23).
7. Prosthesis in accordance with claim 6, characterized in that the said grooves and said tongues extend essentially at right angles to the direction of the femur.
8. Prosthesis in accordance with claim 6 or 7, characterized in that the said grooves and said

tongues extend essentially in parallel to the said patellar sliding surface in the transition area and that the said insert (17) can be locked in different pushed-in positions in relation to the upper prosthesis part.

9. Prosthesis in accordance with one of the claims 4 through 8, characterized in that the said extension (20) of the said insert (17) is designed as a said holding means for a said joint block (30) mounted in the said upper prosthesis part.
10. Prosthesis especially in accordance with one of the claims 1 through 9, characterized in that to secure pushing in (said insert 2, 17) in relation to the said part (said prosthesis part 6) carrying it, one of the said two parts (17) has a said securing hole (27) and the said other part (6) has a said blind threaded hole (34) with a said fixing screw (35), whose head meshes with the said securing bore (27) and has a said expanded collar (36), the said hole (34) containing under the said fixing screw (35) a said compression spring (said rubber plug 37) acting on the said screw.

Specification

The present invention pertains to a knee joint prosthesis with at least one femoral condyle-side joint shell participating in the formation of the patellar sliding surface and an insert extending the said patellar sliding surface in the upward direction.

In the natural knee, the patellar sliding surface is formed, passing over into the joint surfaces in the lower area, by the femoral condyles and extends above the intermediate space between the condyles as a saddle-like depression. When the joint surfaces are replaced by prosthesis shells, these also participate in the formation of the patellar sliding surface. When the upper area of the patellar sliding surface is damaged, it is provided with a special insert, which forms the patellar sliding surface in this area and must join the lower patellar sliding surface area formed by the prosthesis shells continuously. This applies to both prostheses in which only the joint surfaces are replaced by shell-like partial prostheses and total prostheses in which the two joint shells are connected to one another, in general, in one piece and rigidly. To create a continuous transition between the lower and upper areas of the patellar sliding surface formed by the joint shells, it is also known that the joint shells and the part forming the upper patellar sliding surface area are made in one piece. However, since the shapes of knees are subject to rather great differences, this has the drawback that differently shaped prostheses must be kept ready even in case of identical joint shell configurations because of the varying configurations of the patellar sliding surface or difficulties will arise in adaptation. As was mentioned, inserts separated from the joint prosthesis are therefore used, in general, to form the upper area of the patellar sliding surface. However, since continuous adaptation of these inserts to the shape of the surface of the joint shells is difficult, residual symptoms will sometimes develop because of insufficient adaptation.

The basic object of the present invention is therefore to provide a knee joint prosthesis of the type mentioned in the introduction, which guarantees a continuous transition of the patellar sliding surfaces in a simple operation, without requiring a plurality of different prosthesis shapes.

The solution according to the present invention is that the insert is connected to the joint shell or to the joint shells by guide means guaranteeing a continuous sliding transition. These guide means guarantee, on the one hand, the separability or at least a certain mobility of the insert in relation to the joint shells, so that these can be used with the prosthesis parts belonging to them without regard to the upper area of the patellar sliding surface, while they guarantee, on the other hand, easy adaptation to the natural conditions and a continuous transition of the sliding surfaces based on their relative mobility in relation to the joint surfaces or due to their ability to be replaced.

In an advantageous embodiment of the present invention, the guide means are formed by a joint, which is movable about a parallel axis that is essentially parallel to the axis of the knee joint. This joint makes possible a more or less greatly inclined arrangement of the insert in relation to the joint shells, so that this [insert] can be folded simply to the existing front side of the joint bone. In case of a partial prosthesis that is not in the form of joint shells connected to one another in one piece, the joint is advantageously designed such that a certain universal mobility of the joint shells in relation to the insert and at least a motion about an axis extending at right angles to the patellar sliding surface are additionally made possible in order to permit a different relative height adjustment of the joint shells in this manner.

An important field of application of the present invention is total prostheses with an upper, intracondylar prosthesis part, which is bifurcated to receive a joint neck of the lower prosthesis part and has joint shells on both sides of the intermediate space formed by the bifurcation, and a patellar sliding surface [is] formed on these joint shells (by these themselves and/or by separate parts beside these), which said patellar sliding surface is extended above the intermediate space by a separate insert. In such a case, the insert advantageously has an extension, which leads to between the joint shells and carries the guide means. This extension is advantageously bifurcated, so that it participates in the formation of the patellar sliding surface on both sides of the intermediate space. At least part of the lower area of the patellar sliding surface is connected in this manner in one piece to the upper insert, so that a largely transition-free sliding is obtained. Even through the guide means would be able to be formed by a joint pivotable essentially in parallel to the axis of the knee joint in this case as well, a tongue-and-groove connection with a guiding direction extending essentially at right angles to the direction of the femur is preferred. If, according to another feature of the present invention, this guiding direction approximately agrees with the direction of the joint surfaces in the transition area, adaptation to different bone shapes can be performed by the extension of the insert being pushed into the guide means of the upper prosthesis to different extents. The insert can be locked for this purpose in different pushed-in positions in relation to the upper prosthesis part. The statement that the direction of guiding shall extend approximately in parallel to the direction of the patellar sliding surface in the transition area means in this connection that certain angular deviations (up to about 15°) are also permissible, which do not yet bring about any essential stepped offset in case of a different pushed-in position.

In case of a total prosthesis, which has a joint block that is mounted and is to be fixed within the upper prosthesis part, the extension of the insert is advantageously designed as a holding means for this joint block.

The present invention will be explained in more detail below with reference to the drawings, which illustrate advantageous exemplary embodiments. In the drawings,

- Figures 1 and 2 show a perspective view and a front view of a shell-type prosthesis,
- Figure 3 shows a perspective view of a total prosthesis,
- Figures 4 and 5 show a vertical section and a horizontal section, respectively,
- Figures 6 and 7 show a front view and a side view of this prosthesis, respectively, and
- Figure 8 shows a securing means for the insert.

The prosthesis shells 1 shown in Figures 1 and 2, which correspond, for example, to the type explained in DE-PS 1 964 781, are complemented by an insert 2, which extends the patellar sliding surface formed in the lower area of the prosthesis shells 1 in the upward direction. On its edge areas located closest to the joint shells 1, the insert 2 has a projecting pin 3 each, which is received by a hole 4 in the opposite edge of the joint shells. The direction of the pins and of the joint shells is essentially parallel to the extension of the surface of the said parts. The hole 4 is somewhat wider than the pin 3 is thick (indicated in an exaggerated form in the drawing), so that even when the pin meshes with a hole, angular positions are possible, which make possible both a tilting motion about an axis extending in parallel to the knee joint, as is characterized by the second position, indicated

by dash-dotted lines in Figure 1, and a pivoting motion about an axis extending essentially at right angles to the direction of the thigh, so that, as is indicated by dash-dotted lines in Figure 2, different relative height settings of the joint shell are made possible.

The mutual positive-locking meshing prevents an offset in height of the edges of the insert and of the joint shells, which said edges are connected to one another, and hence a continuous gliding transition of the patella. Nevertheless, it is advantageous to round off the edges connected to one another and to optionally approximate their outlines in order for the remaining intermediate space not to be larger than necessary.

It is recognized that the surgical technique is simplified because careful manual adaptation is replaced by the automatic cooperation of the guide means.

The total prosthesis shown in Figures 3 through 7 comprises a lower prosthesis part 5 and an upper prosthesis part 6, which are provided with conventional shafts 7, 8 for fastening in the tibia and in the femur, respectively. The lower prosthesis part 5 has a plate 9, which is to be placed on the joint plateau of the tibia, and a joint cup 10 consisting of a suitable, low-friction plastic, which forms two concave sliding surfaces 11 for the joint shells 12 of the upper prosthesis part. These are carried by the approximately parallelepipedic prosthesis middle part 13, which in turn is connected to the shaft 8. Parts 8, 12 and 13 are made, in general, in one piece from a metal.

The two prosthesis parts are shown in the flexed position of the joint.

An intermediate space, which is limited laterally by the inner surfaces 14 of the joint shells, which said inner surfaces are parallel to one another, is located between the two joint shells 1. These [inner surfaces] are at right angles to the connection surface 15 of the prosthesis middle part 13. A groove 16 is milled into the lateral surfaces 14, directly adjoining the connection surface 15.

The insert 17, which is composed of two lateral, raised areas 18 and a middle, recessed area 19, has a bifurcated extension 20, whose legs 21 are limited on the outside by parallel lateral surfaces 22 each, which carry a rib 23 along their rear edge. The distance between the lateral surfaces 22 is thus smaller than that of the lateral surfaces 14, and the ribs 23 are shaped corresponding to the grooves 16, so that the extension [2]0 can be pushed into the intermediate space between the joint shells 12. While it [the extension - Tr.] is shown in the pulled out, aligned state in Figure 3, Figure 4 shows it the state in which it is pushed in by half, and Figures 6 and 7 show it in the fully pushed-in state.

The front surfaces 24 of the legs 21 are shaped such that they adjoin the surface of the joint shells 12 in the pushed-in state and form, together with these, the lower area of the patellar sliding surface. Their intermediate space 25 is not larger than it is necessary in respect to the width of the joint neck 26 of the lower prosthesis part. The surfaces 24 pass uniformly over into the middle area 19 of the insert, which said middle area is depressed in a saddle-shaped manner. The raised side parts 18 are shaped such that they form the uniform extension of the joint shell surfaces in the pushed-in state. The insert is provided with a hole 27 for receiving a locking screw provided in the prosthesis middle part 13. It would, of course, also be possible to provide any other desired securing means, and these can also make locking possible in different pushed-in positions for adaptation to different bone conditions.

The middle part 13 contains a cavity defined by parallel walls 29 for receiving a joint block 30 made of plastic, which is U-shaped and forms the mounting hole (elongated hole) 31 for the ends of a bolt 32, which is arranged at right angles at the joint neck 26 extending upward from the lower prosthesis part. This joint neck 26 is designed (see Figure 5) as an upright plate, which extends from front to back and forms a lateral guide between the two prosthesis parts in cooperation with the inner surfaces 33 of the joint block 30. The joint block 30 is held by means, not shown, in the middle part 13 laterally by the surfaces 29, upwardly by the wall of the middle part, which said wall is located there, and downwardly by means, not shown, which may comprise, for example, projections in the walls 29 and corresponding recesses in the joint block. The joint block can be removed from the prosthesis middle part in the forward direction and is secured therein by the extension 20 of the insert, which can be pushed, aligned, into a position in front of the front surface of the joint block (Figure 4).

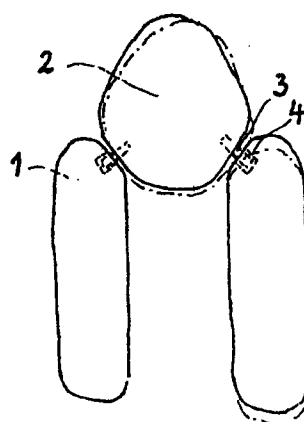
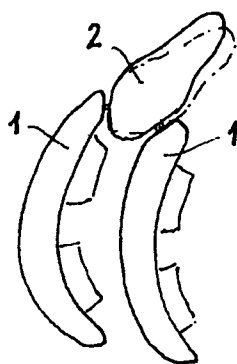
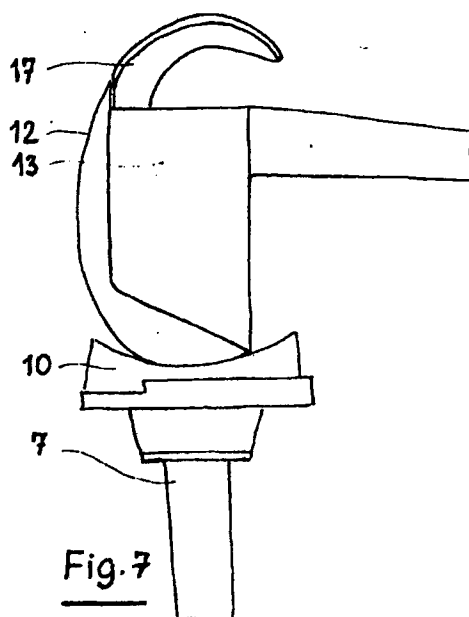
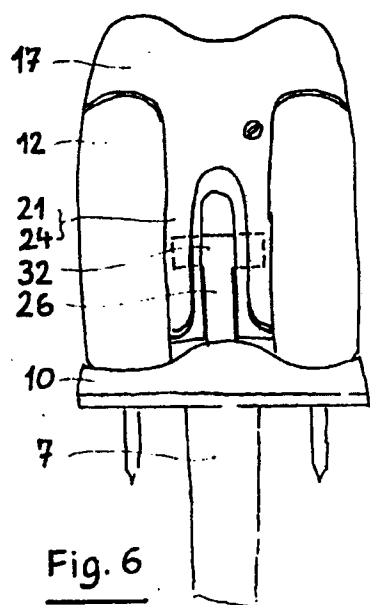
The securing means cooperating with the securing hole 27 is shown in Figure 8. It is recognized that below the securing hole 27, the upper prosthesis part 6 has a blind threaded hole 34, which contains a screw 35, whose head diameter approximately corresponds to the diameter of the securing hole 27. The head is separated from the threaded shank of the screw by a collar 36. A silicone rubber plug 37, whose relaxed diameter is somewhat smaller than the diameter of the hole, is located in the blind hole, so that the screw can be screwed fully into the hole with a corresponding longitudinal compression and lateral strain of the plug and the relaxed length of the said plug is greater than the free length of the hole below the screw when the latter is in the securing state being shown.

When the insert is to be pushed in, the screw is screwed fully into the hole, so that the head of the screw disappears therein. When the insert has been screwed in and the hole 27 is located aligned above the screw 35, the screw is unscrewed to the extent that the collar 36 comes into contact with the lower surface of the insert. The head of the screw then secures the insert in the intended position. The screw itself is secured by the silicone rubber plug 37, which counteracts by its spring force an accidental motion of the screw directed into the hole. The friction present between the silicone rubber plug and the screw acts in the same sense.

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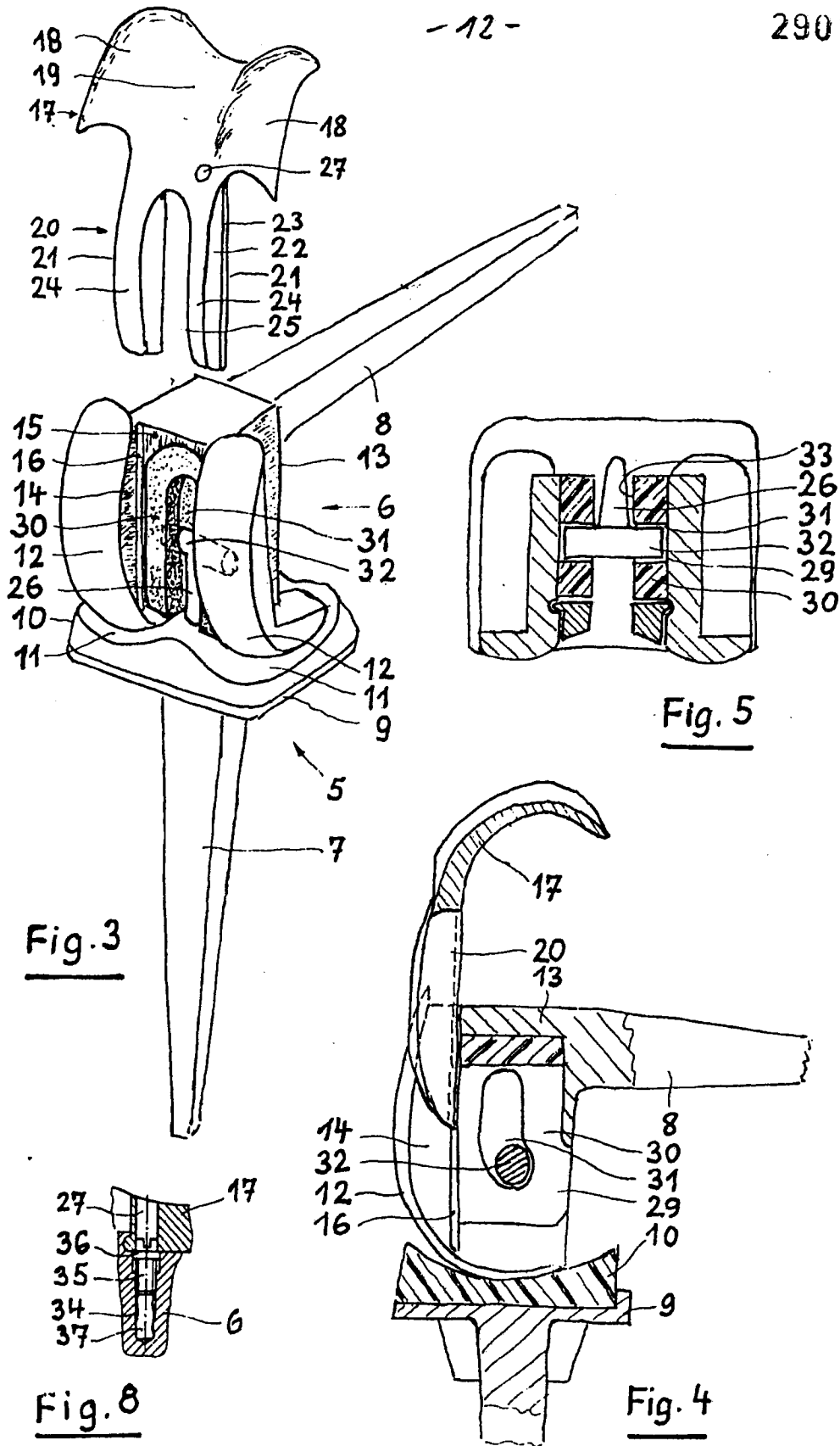
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